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10/031,218	05/07/2002	Marcus Filshie	02597	2627

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EXAMINER
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EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3773

NOTIFICATION DATE	DELIVERY MODE
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09/23/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/031,218	<b>Applicant(s)</b> FILSHIE ET AL.	
	<b>Examiner</b> Darwin P. Erez	<b>Art Unit</b> 3773	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/8/09 has been entered.

### ***Election/Restrictions***

2. Newly submitted claims 28-30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly submitted claims are directed towards a method of controlling the application of a surgical clip, while the originally presented claims are directed towards a clip. Thus, the newly submitted claims and the original claims are related as product and process of use. Since applicant has received an action on the merits for the originally presented invention (the product), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 5, 6, 10, 12, 20 and 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. Claims 5, 6 and 23-26 recite limitations regarding the width of the first and second arcuate shaped portions and the straight portion. However, the written disclosure fails to provide support for the cited limitations. Also, the drawings are not disclosed to be "drawn to scale". Therefore, the limitations of the cited claims raise the issue of new matter.

6. Claim 12 and 20 recite that there is an absence of any straight portion between the first and second arcuate shaped portions. However, there is no support for this negative limitation in the specification and thus raises the issue of new matter.

7. Claim 10 recites the limitation that the pressure is "only" imposed on the straight section. There is no support for this limitation in the specification and thus raises the issue of new matter.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,519,392 to Lingua.

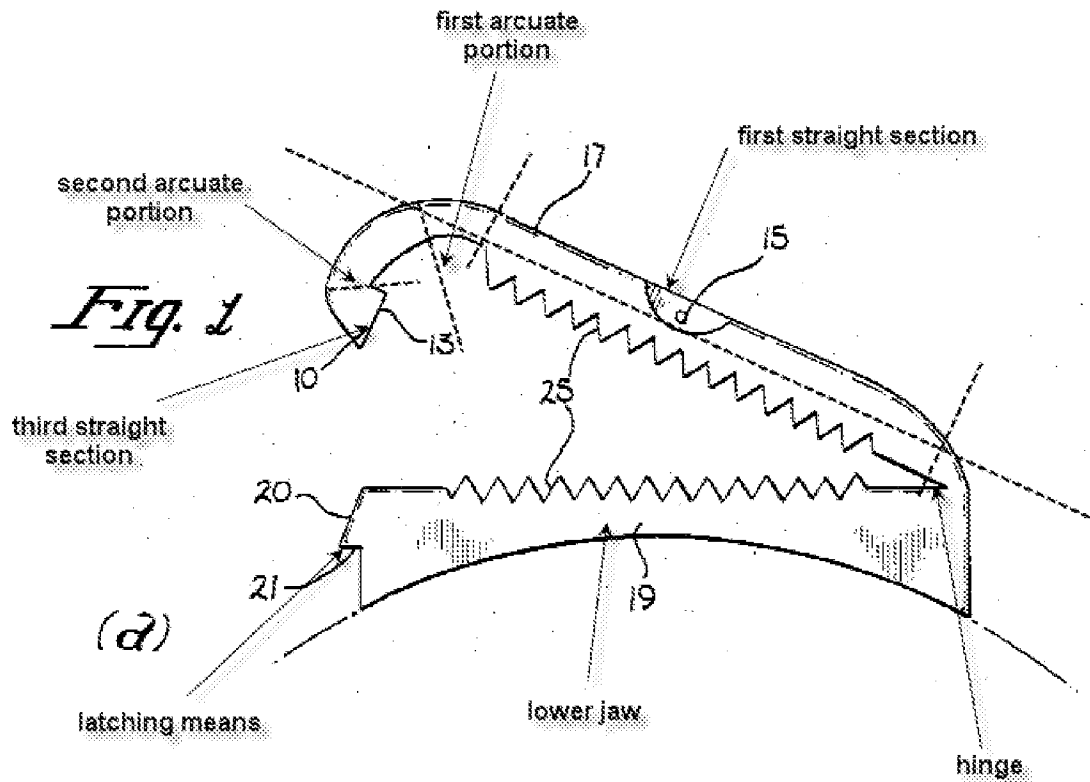
As seen in the attached figure below, Lingua discloses a surgical clip comprising:

- an elongate upper jaw and an elongate lower jaw attached together at a first hinge end;
- the lower jaw being provided with latching means at an opposite end to the hinge;
- the upper jaw comprising a complex shape comprising:
  - a first straight section adjacent to the hinge,
  - a second arcuate shaped section adjoining the straight section and in which the second arcuate shaped section comprises:
    - a first arcuate shaped portion adjacent to said straight section, and
    - a second arcuate shaped portion adjacent to said first arcuate shaped portion at an opposite end of said first arcuate shaped portion to said straight section,

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- wherein the first and second arcuate shaped portions each have an inner and outer surfaces,
- wherein said first arcuate shaped portion having a first radius of curvature on at least its inner contact surface that is substantially greater than the radius of curvature of said second arcuate shaped portion which has a second radius of curvature,
- wherein a center of the radius of curvature for both the first and second arcuate shaped portions is located on the same side of the upper jaw,
- wherein there is an absence of a straight portion between the first and second arcuate shaped portions.

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***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



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13. Claims 1-13, 16, 17 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,519,392 to Lingua in view of US 4,489,725 to Casey et al.

As seen in the attached figure above, Lingua discloses a surgical clip comprising:

- an elongate upper jaw and an elongate lower jaw attached together at a first hinge end;
- the lower jaw being provided with latching means at an opposite end to the hinge;
- the upper jaw comprising a complex shape comprising:
  - a first straight section adjacent to the hinge,
  - a second arcuate shaped section adjoining the straight section and in which the second arcuate shaped section comprises:
    - a first arcuate shaped portion adjacent to said straight section, and
    - a second arcuate shaped portion adjacent to said first arcuate shaped portion at an opposite end of said first arcuate shaped portion to said straight section,
    - wherein the first and second arcuate shaped portions each have an inner and outer surfaces,
    - wherein said first arcuate shaped portion having a first radius of curvature on at least its inner contact surface that is substantially greater than the radius of curvature of said second arcuate shaped portion which has a second radius of curvature,

- wherein a center of the radius of curvature for both the first and second arcuate shaped portions is located on the same side of the upper jaw,
- wherein the first and second arcuate shaped portions are contiguous and have the same width with the straight portion (as seen in Fig. 2); wherein the bottom edge of the device shown in Fig. 2 is viewed as "an inner surface" and the top edge of the device is viewed as the "outer surface", both being flat surfaces (note that the inner and outer surfaces of the straight section has not been clearly defined relative to any other structure),
- a third generally straight section adjacent to said second arcuate shaped portion, said generally straight section, when in the closed position of the clip interlocking under the latching section of the lower jaw;
- wherein the third generally straight section is viewed as the distal generally straight section having a free end that is contiguous with the second arcuate shape section;
- wherein the first arcuate shaped portion has the same width therealong and as measured in the direction of the first radius of curvature;

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- wherein said second arcuate shaped section has the same width therealong and as measured in the direction of the second radius of curvature;
- wherein the upper jaw is distorted to fit within the latch means (see transition from Figs. 3(a) to 3(e);
- wherein the first arcuate shaped portion is contiguous with the second arcuate shaped portion to form a complex contiguous curved shape;
- wherein there is an absence of a straight portion between the first and second arcuate shaped portions;
- wherein the second arcuate shaped section has an arcuate portion on either an outer and inner side thereof.

Lingua discloses all the limitations of the claims except for the clip having a silicone rubber lining on both sides of the jaws; with the first radius of curvature is of the order of three times that of the second radius of curvature; and to the jaws being connected together via a hinge pin.

However, Casey discloses a similar surgical clip having the missing recited limitations. Casey discloses said clip having rubber silicone lining on both sides of the jaws, and wherein the jaws are connected via a hinge pin.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add a silicone lining to the jaws of Lingua as it would provide a softer contact surface for the jaws against the tissue, while the serrated tooth of the jaws will provide enough tension on the lining to secure the clip onto the tissues.

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It also would have been obvious to change the hinge means of Lingua to the hinge means of Casey because both are well known equivalents in the art and substituting one hinge means for another would be a mere obvious design choice to one of ordinary skill in the art.

It also would have been obvious to one of ordinary skill in the art at the time the invention was made to modify curvature of the first or second arcuate shaped portion to have the recited ratio because since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966). It has been held that discovering an optimum value (the ratio of curvature between the first radius of curvature and the second radius of curvature) of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Lingua also discloses the use of a clip closure member (forceps or clamp style tool; col. 2, ll. 14-15) but is silent with regards to the applicator imposing pressure on only the straight section of the clip. However, it would be a mere obvious design choice to one of ordinary skill in the art to modify the device of Lingua to have the applicator only applying pressure on the straight sections of the clip because applying pressure only on the straight portions or only on the curved portions will produce the same result of forcing the clip into a clamped position.

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14. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,519,392 to Lingua in view of US 4,489,725 to Casey et al., as applied to the rejections above, and in further view of US 5,569,274 to Rapacki et al.

The modified device of Lingua discloses all the limitations of the claims except for the use of a tubular storage member/applicator. However, the use of a tubular storage member/applicator for deploying a surgical clip is well known in the art, as shown in Figs. 2A-2B of Rapacki. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the applicator of Rapacki with the clip of Lingua as it allows the surgeon to deliver the clip remotely inside the patient. The tubular member is fully capable of having a dimension that is smaller than a dimension of a captive opening.

***Response to Arguments***

15. Applicant's arguments with respect to claims 14-15 have been considered but are moot in view of the new ground(s) of rejection.

16. Applicant's arguments regarding the rejections under the Lingua reference have been fully considered but they are not persuasive. The applicant argued that Lingua fails to teach a first and second arcuate shaped portions, as amended. However, the examiner had updated the marked up drawing above to clearly show which portions are viewed as the first and second arcuate shaped portions. As shown above, Lingua discloses a first arcuate shaped portion adjacent the straight portion, and a second arcuate shaped portion adjacent the first arcuate shaped portion. Both the first and second arcuate shaped portions have inner surfaces, wherein the inner surface of the first arcuate shaped portion has a larger radius of curvature than that of the second arcuate shaped portion. As for the argument that the combination of Lingua/Casey fails to teach applying a force to only the straight section, the examiner is again noting that it would be obvious to apply force any where along the length of the clip as any position would still allow the clip to close. The applicant's arguments shown in page 10 pertains only to the applicant's embodiment but not to the combination of Lingua and Casey because Casey does not teach a tubular member. Note that 10 merely recites a clip closure member and not a tubular member.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezó whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezó/  
Primary Examiner, Art Unit 3773